

Notice of Allowability	Application No.	Applicant(s)	
	09/734,281	MERCKEN ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE of 6-7-04.
2. ☒ The allowed claim(s) is/are 49-56; renumbered 1-8 respectively
3. ☒ The drawings filed on 12/11/00 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/108,758.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|--|---|

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rebecca Bortolotti on September 1, 2004.

The application has been amended as follows:

In the claims:

Claims 1-48 (Canceled).

Claim 49. (new) A monoclonal antibody that forms an immunological complex with a phosphorylated epitope present in a human abnormally phosphorylated tau protein, wherein the phosphorylated epitope is peptide (a) YS^{*}PG^{*}SPGT (SEQ ID NO:1) or (b) YSSPG^{*}SPGT (SEQ ID NO:2), wherein said peptide is phosphorylated at a position marked with *.

Claim 50. (new) A monoclonal antibody that forms an immunological complex with a phosphorylated epitope present in a human abnormally phosphorylated tau protein, wherein the phosphorylated epitope is a peptide YS^{*}PG^{*}SPGT (SEQ ID NO:1), wherein said peptide is phosphorylated at a position marked with *.

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Claim 51. (new) A monoclonal antibody that forms an immunological complex with a phosphorylated epitope present in a human abnormally phosphorylated tau protein, wherein the phosphorylated epitope is a peptide YSSPG^{*}SPGT (SEQ ID NO:2), wherein said peptide is phosphorylated at a position marked with *.

Claim 52. (new) A hybridoma that secrets any one of the monoclonal antibodies of claims 49, 50 or 51.

Claim 53. (new) A kit comprising: (a) a first monoclonal antibody that forms an immunological complex with a phosphorylated epitope present in a human abnormally phosphorylated tau protein, wherein the phosphorylated epitope is a peptide YS^{*}PG^{*}SPGT (SEQ ID NO:1) or (b) YSSPG^{*}SPGT (SEQ ID NO:2), wherein said peptide is phosphorylated at a position marked with * and (b) a buffer solution.

Claim 54. (new) The kit of claim 53, further comprising a second antibody that binds either normal tau protein or abnormally phosphorylated tau protein, wherein said second antibody binds an epitope that is different from the first monoclonal antibody and wherein said second antibody is selected from the group consisting of a polyclonal antibody and a monoclonal antibody.

Claim 55. (new) The kit of claim 53, wherein the first monoclonal antibody forms an immunological complex with the phosphorylated epitope of YS^{*}PG^{*}SPGT (SEQ ID NO:1).

Claim 56. (new) The kit of claim 53, wherein the first monoclonal antibody forms an immunological complex with the phosphorylated epitope of YSSPG^{*}SPGT (SEQ ID NO:2).

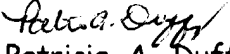
The following is an examiner's statement of reasons for allowance: The combinations over Kosik et al fail because the epitope of Kosik et al encompasses multiple threonine and serine residues all of which may be potentially phosphorylated. None of the serine residues of the Tau-1 epitope was suggested or actually demonstrated to be phosphorylated, at any of the instantly claimed serine residues. Further, Kosik et al does not point to the specific epitope comprising the phosphorylated serine residues claimed herein and casts doubt thereon by teaching that the Tau-1 epitope does not contain any known consensus sequence for any known kinase at the time the invention was made.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia A. Duffy
Primary Examiner
Art Unit 1645



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Fax Cover Sheet

Date: 31 Aug 2004

To: Rebecca A. Bortolotti	From: Patricia A. Duffy
Application/Control Number: 12000,001 09 / 734,281	Art Unit: 1645
Fax No.: 612-332-9081	Phone No.: 571-272-0855
Voice No.: 612-332-5300	Return Fax No.: (703) 872-9306
Re: USSN 09/734,281 proposed ex. amd	CC:
<input checked="" type="checkbox"/> Urgent	<input checked="" type="checkbox"/> For Review
<input type="checkbox"/> For Comment	<input type="checkbox"/> For Reply
<input type="checkbox"/> For Your Request	

Comments:

See attached proposed amendment.

Number of pages 4 including this page

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Application/Control Number: 12/000,001

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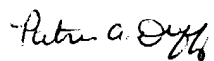
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August 31, 2004

Dear Ms. Bortolotti,

Attached for your review is a proposed amendment to place USSN 09/734,281 in immediate condition for allowance. I look forward to discussing these with you at 3:00 pm on Sept 1, 2004.

Sincerely,

A handwritten signature in cursive script, appearing to read "Patricia A. Duffy".

Patricia A. Duffy

Primary Examiner 1645